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NELSON MULLINS RILEY & SCARBOROUGH LLP
FLOOR 30, SUITE 3000
ONE POST OFFICE SQUARE
BOSTON, MA 02109

EXAMINER	
HILL, KEVIN KAI	

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1633	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/578,402	GLIMCHER ET AL.
	Examiner	Art Unit
	KEVIN HILL	1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 September 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *68-81* is/are pending in the application.

4a) Of the above claim(s) *69,72,74-77 and 79* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *68,70,71,73,78,80 and 81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)	
1) ☒ Notice of References Cited (PTO-892)	4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) ☐ Notice of Informal Patent Application
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.	6) ☐ Other: _____.

Detailed Action

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 9, 2010 has been entered.

Election/Restrictions

Applicant's response to the Requirement for Restriction, filed on July 22, 2009 is acknowledged.

Applicant has elected the invention of Group I, Claims 2-5 and 11-17, drawn to a method for identifying a compound which modulates an interaction between a first and a second polypeptide, the method comprising contacting *in vitro* a non-transgenic cell having a first polypeptide comprising a binding portion of a KRC polypeptide and a second polypeptide comprising a binding portion of a polypeptide selected from the group consisting of GATA3, SMAD or Runx2, classified in class 435, subclass 4.

Within Group I, Applicant has elected the following species, wherein:

i) Claims 1 and 22 are generic to the host cell is a mouse T cell;

ii) determination method steps from the lists recited in claims 9-11 and 13-15, is co-immunoprecipitation (Claim 11);

iii) second polypeptide indicator recited in Claims 1, 4-5 and 22 is GATA3; and

iv) biological activity species that is to be measured from the list recited in Claims 13, 19 and 21 is Th2 cell differentiation.

Amendments

In the reply filed September 9, 2010, Applicant has cancelled Claims 1-67, and entered new claims, Claims 68-81.

Claims 69 and 77 are drawn to non-elected determination method step species, per the recitation of a reporter gene which is an art-recognized heterologous nucleic acid construct (pg 30, lines 8-10, 22-26).

Claims 72 and 74-76 are drawn to non-elected transgenic host cells that properly belong to Group II.

Claim 79 recites a cDNA molecule (SEQ ID NO: 1), and thus is a transgenic nucleic acid molecule that properly belongs to non-elected Group II.

Claims 69, 72, 74-77 and 79 are pending but withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention, there being no allowable generic or linking claim.

This application contains claims drawn to an invention nonelected with traverse in the reply filed on July 22, 2009. Applicant is reminded that the restriction/election requirement was made final in the Office Action of October 7, 2009. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP §821.01.

Claims 68, 70-71, 73, 78 and 80-81 are under consideration.

Priority

This application is a 371 of PCT/US04/36641 filed November 3, 2004, which is a continuation of U.S. application 10/701,401 filed November 3, 2003, which is a continuation-in-part of PCT/US02/14166 filed May 3, 2002. Applicant's claim for the benefit of a prior-filed application parent provisional application 60/288,369 filed May 3, 2001 under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged.

Examiner's Note

Unless otherwise indicated, previous objections/rejections that have been rendered moot in view of the amendment will not be reiterated. The arguments in the September 9, 2010 response will be addressed to the extent that they apply to current rejection(s).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

1. **Claim 68 is objected to because of the following informalities**: the claim recites "a first mammalian KRC polypeptide" and "a second mammalian GATA3 polypeptide", which renders the claim grammatically awkward. The "first" denotes reference to at least a 'second', if not a 'third', 'fourth', etc…., mammalian KRC polypeptide. Similarly, the "second" denotes reference to at least a 'first', if not a 'third', 'fourth', etc...., mammalian GATA3 polypeptide.

However, the claim does not identify the other referenced mammalian KRC and GATA3 polypeptides. The Examiner respectfully suggests cancelling the words "first" and "second".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. **The prior rejection of Claims 1, 11, 13, 16-17, 55, 57-58, 61 and 66 under 35 U.S.C. 112, first paragraph, is withdrawn** in light of Applicant's cancellation of the claims, and in light of Applicant's argument that Claim 68 requires that the KRC and GATA3 polypeptides are mammalian in origin and one of ordinary skill in the art and armed with the teachings of the instant specification could perform the claimed methods in cells which endogenously express one or both of these molecules without undue experimentation, which the Examiner finds persuasive.

Claim Rejections - 35 USC § 103

3. **The prior rejection of Claims 1, 11, 16-17, 55, 57-58 and 66 under 35 U.S.C. 103(a)** as being unpatentable over Emerson (U.S. 2002/0022021; of record) in view of Haenlin et al (1997; of record), Matthews et al (2000; of record), Cubbada et al (1997; of record), (1995; of record in IDS), Wu et al (1996; of record in IDS), Hicar et al (2001; of record in IDS) and Ting et al (1996; of record) **is withdrawn** in light of Applicant's cancellation of the claims.

4. **Claims 68, 71, 73, 78 and 80 are rejected under 35 U.S.C. 103(a)** as being unpatentable over Emerson (U.S. 2002/0022021; of record) in view of Haenlin et al (1997; of record), Matthews et al (2000; of record), Cubbada et al (1997; of record), (1995; of record in IDS), Wu et al (1996; of record in IDS), Hicar et al (2001; of record in IDS) and Ting et al (1996; of record).

While Applicant has changed the claim numbers with the new claim set, the limitations of instant Claims 68, 71, 73, 78 and 80 were recited in prior Claims 1, 11 and 57 and previously rejected. The disclosure of the cited prior art is provided in prior Office Actions and will not be iterated herein.

Response to Arguments

Applicant iterates arguments from a prior Response to Amendment (February 4, 2010).

The Examiner's response to Applicant's iterated arguments are discussed in the prior Office Action. The Examiner's response to new arguments will be discussed below.

Applicant argues that at the time of filing, it was well known in the art that only one of the two Ush CCHC fingers disclosed in Figure 6 actually binds to Drosophila GATA-1 homologue (see Figure 1 of Liew et al, submitted herewith as Appendix A). Thus, from the available data it could not have been predicted whether a Shn CCHC zinger finger will bind to the Drosophila GATA-1 homologue, let alone whether KRC will bind to GATA-3.

Applicant's argument(s) has been fully considered, but is not persuasive. Applicant is again reminded that a copy of Liew et al (Appendix A) and Tsai et al (Appendix B) have not been provided to the Examiner for evaluation. It would be remedial for Applicant to make said references of record, and it is unclear why Applicant has failed to do so presently even after being informed of the deficiency in the prior Office Action.

Applicant argues that none of the cited references teach or suggest that inhibition of the interaction between KRC and GATA3 would result in the inhibition of Th2 cytokine promoter activation. Haenlin teaches that transcriptional activity of Pannier is negatively regulated by heterodimerization with Ush, and the instant specification discloses that neither Shn-1 nor Shn-2 could augment GATA3-dependent IL-5 promoter activation.

Applicant's argument(s) has been fully considered, but is not persuasive. The phrases "to thereby downmodulate transcription of at least one Th2 cytokine gene" and "to thereby identify a compound which downmodulates an interaction between a first mammalian KRC polypeptide and a second mammalian GATA3 polypeptide to thereby downmodulate transcription of at least one Th2 cytokine gene" are considered intended use limitations of the compound identified that downmodulates an interaction between a mammalian KRC polypeptide and a mammalian GATA3 polypeptide.

A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the

claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The phrase "to thereby downmodulate transcription of at least one Th2 cytokine gene" is an intended use limitation, which does not contain any further structural limitations with respect to claimed compound identified by its ability to downmodulate an interaction between KRC and GATA3 (see MPEP §2114). Absent evidence to the contrary, any compound identified to downmodulate an interaction between KRC and GATA3 will necessarily downmodulate transcription of at least one Th2 cytokine gene. "Products of identical chemical composition cannot have mutual exclusive properties." A compound and its properties are inseparable (*In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)). Any properties exhibited by or benefits from are not given any patentable weight over the prior art provided the composition is inherent. A chemical composition and its properties are inseparable.

5. **The prior rejection of Claims 13 and 61 under 35 U.S.C. 103(a)** as being unpatentable over Emerson (U.S. 2002/0022021; of record) in view of Haenlin et al (1997; of record), Matthews et al (2000; of record), Cubbada et al (1997; of record), (1995; of record in IDS), Wu et al (1996; of record in IDS), Hicar et al (2001; of record in IDS) and Ting et al (1996; of record), as applied to Claims 1, 11, 16-17, 55, 57-58 and 66 above, and in further view of Lee et al (1998; of record) **is withdrawn** in light of Applicant's cancellation of the claims.

6. **Claims 70 and 81 are rejected under 35 U.S.C. 103(a)** as being unpatentable over Emerson (U.S. 2002/0022021; of record) in view of Haenlin et al (1997; of record), Matthews et al (2000; of record), Cubbada et al (1997; of record), (1995; of record in IDS), Wu et al (1996; of record in IDS), Hicar et al (2001; of record in IDS) and Ting et al (1996; of record), as applied to Claims 68, 71, 73, 78 and 80 above, and in further view of Lee et al (1998; of record) and Wu et al (Nucleic Acid Res. 21(22):5067-5073, 1993).

Determining the scope and contents of the prior art.

Neither Emerson, Haenlin et al, Matthews et al, Cubbada et al, Wu et al, Hicar et al nor Ting et al teach *ipsis verbis* the step of determining the ability of the compound to modulate Th2 cell differentiation.

However, Ting et al taught that GATA-3 is involved in T cell development (Abstract; pg 475, col. 1, ¶2). Similarly, Lee et al taught that IL-5 is restricted to the Th2 subset of helper T cells, and that a *cis*-regulatory element of the IL-5 promoter that confers Th2-specific expression is recognized by GATA3, which itself is preferentially expressed in Th2 cells (Abstract).

Furthermore, Wu et al suggest that KRC is involved in T cell development (pg 5071).

Considering objective evidence present in the application indicating obviousness or nonobviousness.

It would have been obvious to one of ordinary skill in the art to modify the method of identifying a compound which modulates an interaction between a mammalian KRC polypeptide and a mammalian GATA-3 polypeptide to further comprise the step of determining the ability of the compound to modulate Th2 cell differentiation with a reasonable expectation of success because those of ordinary skill in the art had long recognized that KRC may be involved in T cell development and GATA-3 is involved specifically in Th2 cell development.

The cited prior art meets the criteria set forth in both *Graham* and *KSR*, and the teachings of the cited prior art provide the requisite teachings and motivations with a clear, reasonable expectation of success. Thus, absent evidence to the contrary, the invention as a whole is *prima facie* obvious.

Conclusion

7. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KEVIN K. HILL whose telephone number is (571)272-8036. The examiner can normally be reached on Monday through Friday, between 9:00am-5:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph T. Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin K. Hill/
Examiner, Art Unit 1633